

Date: April 28, 2016  
To: Faculty Senate  
From: Tatiana Kaminsky, Institutional Review Board Chair

## 2015-2016 Institutional Review Board Final Report

### **INTRODUCTION**

This report summarizes the work undertaken by the Institutional Review Board (IRB) during the 2015-2016 academic year.

The IRB exists for the purpose of protecting the rights, health, and well-being of humans solicited and volunteering for participation as research subjects. In the context of reviewing proposed research studies involving human subjects, the IRB gives very careful attention to issues such as potential risks to participants, protection of participants' identities and disclosed information of a sensitive nature, safety, ethical recruitment practices, and the accessibility and adequacy of informed consent.

This academic year the Institutional Review Board reviewed 121 proposals. Of these 10 were full board (7 approved, 2 pending, 1 withdrawn), 106 were expedited (93 approved, 12 pending, 1 withdrawn), and 5 were exempt (5 approved). In addition, the board focused on completing the two formal Senate charges as discussed below.

2015-16 IRB membership: Tatiana Kaminsky (chair), Lisa Ferrari (ex-officio), Tim Beyer, Joel Elliott (Fall), Jung Kim (Spring), Mita Mahato, Sarah Moore, Brad Richards, Barbara Warren, and Troy Christensen (community representative). As chair, I would like to personally thank each member for his/her diligence in completing timely and thorough reviews, in addition to attending to additional committee work.

### **CHARGES**

In addition to reviewing the research protocols that were submitted to the IRB, committee members addressed two Senate charges this year.

1. Establish guidelines for the use of CITI training modules at Puget Sound. Broadcast or otherwise disseminate information about those guidelines and procedures to relevant portions of the campus community.

The university has access to a number of training modules created by The Collaborative Institutional Training Initiative (CITI) at the University of Miami (<https://www.citiprogram.org>). Some of these training modules outline issues related to research with human subjects, including ethics, the role of the IRB, and informed consent, among others. Over the past couple of years, the members of the IRB have explored the value of these training modules as a quick and informative tutorial for researchers conducting human research. After careful deliberation this year, we have decided to require all students

who submit protocols to the IRB to complete a single student training module. We anticipate that the training module will take students approximately 45 minutes to complete. The link to the training, along with detailed instructions, will be available on the IRB website soon.

There are a several reasons that we are implementing this change. The first, and most important, is to ensure that there is a university-wide standard that is followed when educating students about their ethical and legal responsibilities when conducting research with human subjects. We understand that some faculty members include information about these topics in their classes, but this has not been universal across campus. Use of the CITI training module will ensure a consistent foundation for student education in this area.

The second reason is that requiring a basic level of training allows us to comply with federal regulations and expectations of institutions where human research is conducted. It also keeps us in step with practices at peer institutions. Last year, Dr. Lisa Ferrari communicated with IRB Chairs or other administrators at our comparison schools, in addition to Pacific Lutheran University and Seattle University, about their IRB process. Eight of the twelve (Denison, Lewis & Clark, Linfield, Pacific Lutheran University, University of Portland, Reed, Seattle University, and Willamette) require people submitting IRB applications for human subjects research to complete formal training.

Our final reason for this change is to assist students in navigating the IRB process. We have noticed frequent errors in the protocols we have received from students, including issues with obtaining fully informed consent, determining the appropriate type of review (exempt, expedited, or full board), identifying risk and steps that will be taken to mitigate it, and ensuring confidentiality. We hope that completing the CITI training will speed the IRB review process for students by enabling them to avoid common errors.

This change will be implemented with protocols that are submitted in AY1617. Students submitting proposals after August 28, 2016 will need to have completed the CITI student training module. The Associate Deans' office will ensure that all student researchers listed as investigators have completed the training before their protocols will be forwarded to IRB members for review. As stated above, further details about how to set up a CITI account and access the training modules will be posted on the IRB website soon.

The IRB will monitor this change during the next academic year. Members of the IRB will also make decisions about a number of the supplementary training modules that are available through CITI. We anticipate that additional training modules will need to be completed for students conducting certain types of research, such as with special populations (e.g., children or prisoners) and/or international research. Required use of the training modules by faculty and staff members who are submitting IRB proposals will also be considered. The members of this year's IRB agreed that a gradual implementation was the best course of action.

To communicate this change, I sent individual messages to faculty members and departmental directors from the departments that utilize the IRB most frequently, including Occupational Therapy, Physical Therapy, Exercise Science, Psychology, Sociology and Anthropology, and Business. We are also working on making the information readily

available on the IRB website. When the website changes have been made, we will send a brief announcement about the change to the faculty as a whole through the Faculty Listserv. In addition, there will be separate faculty/staff and student cover pages that will be submitted with research protocols. The student cover pages will have a place for students to indicate that CITI training has been completed (see Appendix A).

2. Maintain an awareness of IRB procedure and purview on other liberal arts campuses (including the NW5C), with particular attention to how other campuses navigate non-clinical research proposals (ethnography, oral history), student projects, journalism, and research outside the United States.

During AY1415, representatives from the IRB worked with Dr. Andrew Gardner from Sociology and Anthropology (SOAN) and Dr. Nancy Bristow from History to create a Memorandum of Understanding (MOU) about research that is submitted to the IRB that makes use of ethnography and/or oral history. A draft of the MOU was created but was not voted on or approved during the last academic year.

This year, we continued the work on the MOU. We communicated with Dr. Gardner regularly about the outstanding questions the IRB members had about the MOU. One of the larger questions was about assessment of risk and steps that would be taken if adverse situations arose. Current members of the IRB were concerned those issues were not adequately addressed in the draft of the MOU. Dr. Gardner attended an IRB meeting in February and some additional changes were made to the draft of the MOU, with a number of points clarified.

The members of the IRB then pilot tested the MOU with the SOAN protocols we received during the spring. After the trial period, the members of the IRB revisited the MOU. We also reached out to Dr. Gardner to ask if there were additional changes that were recommended by the faculty in SOAN. Final revisions were made to the MOU and it was approved for use on April 22, 2016. Please see Appendix B for the approved MOU.

## **RECOMMENDATIONS FOR FUTURE CHARGES**

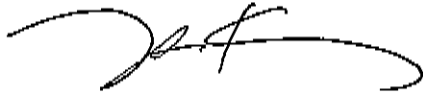
There were a number of issues that arose during this academic year that the IRB suggests as potential charges for future academic years. They are as follows:

1. Follow up with the CITI training modules, with decisions made about which additional modules will be requested and for whom. For example, it may be beneficial for researchers conducting studies with special populations (e.g., children or prisoners) or for those conducting international research to complete additional training modules. The use of the CITI system with faculty and staff also needs further consideration.
2. The IRB received numerous requests from researchers off campus this year. There are additional considerations for research that is conducted with members of the campus community by people who are not on campus, including oversight and recruitment. We recommend that this issue be considered in more depth by future IRB committees.

Questions to ask include whether or not an on-campus sponsor/partner should be required and whether or not there are additional steps or procedures that need to be followed when these researchers submit IRB protocols.

3. There have been some issues with continuity as new IRB members join the committee each year. For example, a system that educates new members about review procedures, including the existence of Memoranda of Understanding would be helpful. Other issues include the need for regular review of existing Memoranda of Understanding, follow up with researchers to ensure that closure forms are submitted after research is complete, etc. Clearer procedures to facilitate the transition between academic years may be warranted and should be explored in more depth.
4. Further consideration about the unique issues that arise for international research would be beneficial. Some of these issues include adequate supervision for students conducting international research, translation and back translation of documents (e.g. consent forms) when research is conducted with populations that speak a language besides English, issues related to cultural differences in the informed consent process, etc.

Respectfully submitted by:  
Tatiana Kaminsky, PhD, OTR/L  
Chair of the IRB AY1516

A handwritten signature in black ink, appearing to be 'TK', with a long horizontal flourish extending to the right.

## **APPENDICES**

### **Appendix A: Updated Student Cover Page**

See following page

UPS IRB PROTOCOL # \_\_\_\_\_

**University of Puget Sound INSTITUTIONAL REVIEW BOARD  
Application for Approval of Research Involving Human Subjects  
(Cover Sheet)**

*(Protocols meeting Full Board Review must be submitted two weeks prior to the date of the IRB meeting on which the review is to occur.)*

Please Check One:  New Project  Renewal  Modification *(Attach Renewal/Modification Form)*

Date of Submission: \_\_\_\_\_

Protocol Title: \_\_\_\_\_

CITI training completed:

Principal Investigator: Typed name: \_\_\_\_\_ Yes  No   
Signature: \_\_\_\_\_  
Department or School: \_\_\_\_\_  
Email: \_\_\_\_\_  
Telephone number: \_\_\_\_\_

Co-Investigator: Typed Name: \_\_\_\_\_ Yes  No   
Signature: \_\_\_\_\_  
Email: \_\_\_\_\_

**Faculty Advisor's Statement** (student projects only): I, \_\_\_\_\_ am the advisor for \_\_\_\_\_  
\_\_\_\_\_. My signature below indicates that I have read the attached protocol and have checked the contents with the IRB Guidelines. I thereby recommend this protocol as:  
Exempt Review  Expedited Review  Full Board Review   
Signature: \_\_\_\_\_ Email: \_\_\_\_\_

Source of Support (if any): \_\_\_\_\_

Level of Risk to Human Participants:  Minimal  Greater than minimal

Number of Participants: \_\_\_\_\_

Are vulnerable populations involved?\*  yes  no Are children involved?\*  yes  no

\*Normal participants are (a) over the age of 18 (b) able to make independent decisions with full mental capacity. Children are minors under the age of 18.

Has this proposal been or will it be submitted to other Human Subjects Review Boards, departmental committees, or community agencies for review and approval?  
 Yes (attach approval letters)  No

## Appendix B: Memorandum of Understanding between SOAN and the IRB

### Department of Sociology and Anthropology Memorandum of Understanding with the Institutional Review Board

This memorandum of understanding (MOU) outlines special considerations of research conducted by the Department of Sociology and Anthropology and how these considerations apply to protocol creation and review by the IRB. Ethnographic research, traditionally employed in Anthropology, is now in wide use across a variety of academic disciplines in the humanities and social sciences, including Sociology, Religious Studies, Political Science, and numerous other disciplines and interdisciplines. It commonly utilizes several methods that necessitate IRB exceptions. Those exceptions are described here.

1. *Participant-observation* is a core method in the ethnographic toolkit (Malinowski 1922; Bernard 2011). The strengths of this method rest in the capacity of the researcher to enter and assess human's normal, everyday, quotidian, collective social activities. Human subjects in these contexts are protected by the anonymity of these encounters. Based on these features, participant observation may be exempt from requiring informed consent (written or verbal) if the level of risk of the proposed is minimal. If the level of risk of the proposed study is more than minimal, informed consent may not be waived. The researcher should endeavor to clearly articulate the subjects' level of risk in relation to participant-observation and the overall research topic.
2. Ethnographic research frequently employs interviews. These interviews can be divided into four basic types: *informal interviews*, *unstructured interviews*, *semi-structured interviews*, and *structured interviews* (Bernard 2011). All submitted protocols should clearly specify what types of interviews will be utilized.
  - A. In ethnography, *informal interviews* are the casual interactions resulting amidst participant observation. Names and identities are not collected, and these informal interactions do not require specific IRB approval, but are approved generally as participant-observation (see point 1, above).
  - B. If *structured interviews* are to be used, the predetermined set of questions must be included with the protocol.
  - C. If *semi-structured interviews* are to be used, an *interview guide* (Bernard 2011) comprising a basic outline of topics to be covered over the course of the interview must be included with the protocol. This basic outline should delineate the range of topics the researcher intends to cover the semi-structured interviews.
  - D. If *unstructured interviews* are to be used, the general research topic guiding these unstructured interviews will be specified.
3. Ethnographic research may waive written consent if verbal consent is the preferred option. Protocols need not specify why written consent is waived as long as the process for obtaining

verbal consent is delineated on a script. Verbal consent scripts must describe key participation and consent issues. Upon completion of the verbal consent process, the researcher signs and dates the verbal consent script indicating that consent has been obtained from the participant.

4. In articulating the risks human subjects potentially face as a result of participation in the ethnographic project described in the protocol, student researchers should describe a reasonable range of possible risks that might be encountered as a result of the interview agenda. Student researchers should identify situations in which their professor will be consulted, in addition to identifying other strategies for addressing potentially risk-laden responses to interview questions and interactions.
5. Oral histories are the collection and study of histories from individuals with firsthand memories and experiences with the event or period in question. As such, oral history does not meet the federal definition of “research” in the sense of developing or contributing to generalizable knowledge. However, the University of Puget Sound IRB will require projects to be submitted for review. These projects are designated for exempt status, except in situations where the population or the area of inquiry will directly result in more than minimal risk to participants.

#### References Cited

Bernard, Russell (2011) *Research Methods in Anthropology*. Fifth Edition. Walnut Creek, CA: AltaMira Press.

Malinowski, Bronislaw (1922) *Argonauts of the Western Pacific: An account of native enterprise and adventure in the Archipelagoes of Melanesian New Guinea*. London: G. Routledge & Sons.

This MOU has an expiration date of April 22, 2019, at which time it will be reviewed by both the IRB and the Department of Sociology and Anthropology for renewal. The Department of Sociology and Anthropology should direct any questions about this MOU to the current Chair of the IRB or, if that person is unavailable, the Associate Deans.

Date: April 22, 2016

Owned by: Department of Sociology and Anthropology